

multiple samples or multiple analytes in parallel. Each fluidic zone is separated from the adjacent fluidic zone by a diffusion barrier.

[0052] A “diffusion barrier” is a structure to minimize diffusion or convectance of the contents of one fluidic zone to the next fluidic zone, such that the majority of the contents that move from one zone to the next fluidic zone are moved by directed fluidic flow and/or by activating the magnetic micro-coil array. Diffusion barriers can be created, for example, by elongating the channel, groove, opening or conduit (“the path of the fluidic zone”), narrowing the path, angling the path of the fluidic zone, or any combination thereof. Diffusion barriers can also comprise a physical barrier, such as thermally-sensitive barrier. A “thermally-sensitive barrier” is a physical barrier that becomes permeable due to the application of heat. For example, a thermally-sensitive barrier can comprise a gel that melts when heated and thus allows the contents of one fluidic zone to pass through to the next zone. Hydrophilic fluid or liquid can be contained in a shape of droplets surrounded by hydrophobic liquid such as silicone oils to form strong diffusion barriers through hydrophilic-hydrophobic interactions so that droplets can be separated and transported without mixing with other fluids as demonstrated in J. Micro-mech. Microeng. (2006) 16:1875 and Sensors and Actuators B (2006) 113:563. A diffusion barrier can be accomplished by “particle trapping and transport” through DEP (dielectrophoresis) as demonstrated in Biophysical Journal (1998) 74:1024 and Sensors and Actuators A 121 (2005) 59. In yet another aspect, the diffusion barrier can be created by a MEMS membrane valve.

[0053] The sample zone comprises a space for holding a sample, and is selected from a reservoir, a channel, an opening, a surface, or a combination thereof. In one embodiment, there is an inlet for allowing the insertion of a sample into the zone, and a vent to allow air or gas to exit as the sample is introduced. In a further embodiment, the vibration element is activated to vibrate the fluid within the sample zone and deaggregate the magnetic particles, signal particles, analyte, and/or binding complexes, in order to facilitate interaction between these components and allow for separation of unbound components from the binding complexes.

[0054] The cleaning zone is a reservoir, channel, groove, opening, or conduit connecting the sample zone and the detection zone, which is preferably separated from the sample zone and detection zone by diffusion barriers. In one embodiment, an additional reaction between an analyte and a magnetic particle and/or a signal particle can occur in this zone. In other embodiments, this zone provides a region whereby the magnetic particles and binding complexes are separated from unbound analyte or other components of the sample, and/or unbound signal particles. In a further embodiment, the cleaning zone can comprise an affinity surface that is typically

complementary to the affinity agent attached to the magnetic and/or signal particle, such that the particles are essentially immobilized in this zone.

[0055] The detection zone is a reservoir, channel, groove, opening, or conduit in association with a detection element. It may comprise an array of capture molecules, as described in more detail below. The detection element can be an optical detection element or an electrical detection element. In certain embodiments, the optical detection element is selected from a Raman detector, a photon multiplier tube, a fluorescent reader, or an electrochemical sensor and the electrical detection element is selected from a FET element, a capacity detection element, a current sensor, and a charge sensor. Typically, the detection of the binding complex or the signal analyte complex indicates the presence of the analyte.

[0056] In further embodiments, the detection zone comprises a reaction substrate. A “reaction substrate” is a material or substance upon which an enzyme (such as the catalytic element) acts. The product of the reaction can be fluorogenic, chemiluminescent, or detectable by UV-visible light (such as by a color change). Non-limiting examples of reaction substrates include Lumigen APS-5, Lumigen TMA-6, Lumigen PS-atto, Lumigen PS-3, H₂O₂ with an oxidizable compound, Amplex Red, 3, 5, 3', 5'-tetramethylbenzidine (TMB), glucose, O₂, ATP, Mg²⁺, luciferin, ino-luciferin, quinolinyl, coelentrastazine, aldehyde, FMNH₂, and analogs and combinations thereof.

[0057] Typically, if the detection zone comprises a reaction substrate, the magnetic affinity complex and/or the signal affinity complex comprises a catalytic element. The “catalytic element” is an external compound that serves as an agent to cause a chemical reaction to occur in the reaction substrate, which reaction product is detectable by the detection element. In certain embodiments, the catalytic element is selected from the group consisting of alkaline phosphatase, horseradish peroxidase, glucose oxidase, luciferase (from firefly, Renilla, bacteria, or other sources) or analogs or combinations thereof.

[0058] The catalytic element can be conjugated to the signal particle through a functionalized polymer. For example, a polymer with a functional group (i.e. aldehyde, amine, carboxylic acid, biotin) is used to conjugate the affinity agent and/or catalytic element to the particle. Conjugation can be through non-covalent interactions such as hydrophobic or electrostatic interactions, or through covalent interactions, such as amide bond formation.

[0059] Additionally, the fluidic zones of the device can contain an appropriate buffer to permit the reaction to occur.

[0060] Examples of non-limiting catalytic element-reaction substrate combinations and the method for detecting the reaction product are shown in Table 1.

TABLE 1

Examples	Catalytic element	Substrate	Signal	Detection
1	Alkaline phosphatase (AP)	Lumigen APS-5 and others	Light (450 nm).	Photo sensor
2	Horse-radish peroxidase (HRP)	Lumigen PS-atto, Lumigen TMA-6, Lumigen PS-3, etc	Light	Photo sensor
		H ₂ O ₂ , oxidizable compound	Electron	Electrical sensor
		Amplex Red (10-acetyl-3,7-dihydroxyphenoxazine) + H ₂ O ₂	Fluorescence from resorufin	excitation at 530-571 nm, emission at 590-600 nm
		3,5,3',5'-tetramethylbenzidine	Absorption (450 nm)	UV-Vis